

§ 640.1

21 CFR Ch. I (4-1-01 Edition)

Subpart J—Immune Globulin (Human)

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AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

SOURCE: 38 FR 32089, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21-12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

Subpart A—Whole Blood

§ 640.1 Whole Blood.

The proper name of this product shall be Whole Blood. Whole Blood is defined as blood collected from human donors for transfusion to human recipients.

[38 FR 32089, Nov. 20, 1973, as amended at 50 FR 4138, Jan. 29, 1985]

§ 640.2 General requirements.

(a) *Manufacturing responsibility.* All manufacturing of Whole Blood, including donor examination, blood collection, laboratory tests, labeling, storage and issue, shall be done under the supervision and control of the same licensed establishment except that the Director, Center for Biologics Evaluation and Research, may approve arrangements, upon joint request of two or more licensed establishments, which he finds are of such a nature as to assure compliance otherwise with the provisions of this subchapter.

(b) *Final container.* The original blood container shall be the final container and shall not be entered prior to issue for any purpose except for blood collection. Such container shall be uncolored and transparent to permit visual in-

spection of the contents and any closure shall be such as will maintain an hermetic seal and prevent contamination of the contents. The container material shall not interact with the contents under customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, or potency of the blood.

(c) *Reissue of blood.* Blood that has been removed from storage controlled by a licensed establishment shall not be reissued by a licensed establishment unless the following conditions are observed:

(1) The container has a tamper-proof seal when originally issued and this seal remains unbroken;

(2) A segment is properly attached and has not been removed, except that blood lacking a properly attached segment may be reissued in an emergency provided it is accompanied by instructions for sampling and for use within 6 hours after entering the container for sampling;

(3) The blood has been stored continuously at 1 to 6 °C and shipped between 1 and 10 °C;

(4) The blood is held for observation until a significant inspection consistent with the requirements of § 640.5(e) can be made.

(d) *Issue prior to determination of test results.* Notwithstanding the provisions of § 610.1 of this chapter, blood may be issued by the manufacturer on the request of a physician, hospital, or other medical facility before results of all tests prescribed in § 640.5, the test for hepatitis B surface antigen prescribed in § 610.40(a) of this chapter, and a test for antibody to Human Immunodeficiency Virus (HIV) prescribed in § 610.45(a) of this chapter have been completed, where such issue is essential to allow time for transportation to ensure arrival of the blood by the time it is needed for transfusion: *Provided*, That (1) the blood is shipped directly to such physician or medical facility, (2) the records of the manufacturer contain a full explanation of the need for such issue, and (3) the label on each